IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC., and NEW YORK UNIVERSITY	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No.**
	)	
CELLTRION HEALTHCARE CO., LTD., CELLTRION, INC., and HOSPIRA, INC.	)	
Defendants.	)	
	)	

COMPLAINT

Plaintiffs Janssen Biotech, Inc. ("Janssen") and New York University ("NYU") (together "Plaintiffs") for their Complaint against Defendants Celltrion Healthcare Co., Ltd., and Celltrion, Inc. ("Celltrion") and Hospira, Inc. ("Hospira") (together "Defendants") allege as follows.

NATURE OF THE ACTION

1. This is one of the first actions for patent infringement under 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 in the part of the Patient Protection and Affordable Care Act known as the Biologics Price Competition and Innovation Act ("BPCIA").

2. This is also an action to enforce the patent dispute resolution provisions of the BPCIA, which Defendants have refused to follow to date and in fact have repeatedly sought to circumvent. Had Defendants obeyed the statutory requirements, the patents asserted in this Complaint might never have needed to be asserted, or might not have needed to be asserted in their current form.

3. However, Defendants have insisted that Plaintiffs file this lawsuit before the conclusion of the BPCIA dispute resolution process and have threatened to seek penalties under the BPCIA if Plaintiffs fail to do so. Although Plaintiffs believe that Defendants' demand

violates the BPCIA, Plaintiffs file this suit to protect their rights and to obtain an order compelling Defendants to comply with the provisions of the BPCIA.

4. The BPCIA created an abbreviated regulatory pathway for the approval of biosimilar versions of biological medicines. The BPCIA pathway allows biosimilars makers to avoid the full complement of pre-clinical and clinical studies required for regulatory approval and instead rely on data supporting the safety and efficacy of the innovative biological product which the biosimilar mimics. By taking advantage of the BPCIA regulatory pathway, biosimilars makers can greatly reduce the time and expense of obtaining marketing approval.

5. In order to prevent the new biosimilar pathway from undermining the intellectual property rights of innovators and thereby deterring innovation, the BPCIA also created an intricate and carefully orchestrated set of dispute resolution procedures to facilitate the orderly resolution of patent disputes before a biosimilar product could enter the market.

6. Pursuant to the BPCIA, Defendants submitted an abbreviated Biologic License Application ("aBLA") seeking permission to market a proposed biosimilar version of Janssen's revolutionary biological medicine Remicade® (infliximab).

7. Defendants' aBLA was accepted for review by the Food and Drug Administration ("FDA"), but FDA has not yet approved the application or given any indication whether it will be approved, when it will be approved, or what the scope of any approval will be.

8. To avoid burdening the Court and parties with unnecessary disputes, the BPCIA requires a series of information exchanges and good-faith negotiations between the parties before the filing of a patent infringement lawsuit. Defendants, however, have refused to follow these procedures. After bringing two premature (now dismissed) declaratory judgment actions outside of the provisions of the BPCIA, Defendants have sought to short-circuit the BPCIA process by

withholding required information, refusing to participate in required procedures, and threatening to seek penalties if Plaintiffs did not file this action before the time called for by the BPCIA.

9. Defendants have further thwarted the BPCIA patent dispute resolution process by serving a premature "notice of commercial marketing." Under the BPCIA, a biosimilar applicant must serve a notice of commercial marketing at least 180 days before marketing a licensed biosimilar product. The purpose of this provision is to ensure adequate time to adjudicate a possible preliminary injunction motion before a licensed biosimilar product enters the market.

10. In serving a purported "notice of commercial marketing" before their biosimilar product is licensed and before the parties have engaged in the statutorily mandated good-faith negotiations regarding Plaintiffs' patents, Defendants effectively deprived Plaintiffs of the statutory time period for considering the need for, and adjudicating, a potential preliminary injunction motion.

11. Although an action for patent infringement is premature under the BPCIA, in light of Defendants' actions, Plaintiffs are asserting, in addition to their claims for violations of the BPCIA, claims for infringement of six patents under 35 U.S.C. § 271(e)(2)(C). Plaintiffs assert infringement under 35 U.S.C. § 271(e)(2)(C)(i) of three patents based on Defendants' submission of the aBLA for marketing approval of their proposed biosimilar product. Plaintiffs assert infringement under 35 U.S.C. § 271(e)(2)(C)(ii) of three additional patents based on Defendants' submission of the aBLA and their failure to provide manufacturing information in addition to the aBLA itself as required under the BPCIA.

PARTIES

12. Janssen Biotech, Inc. ("Janssen") is a company organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business in Horsham, Pennsylvania.

13. New York University ("NYU") is a research university organized as a corporation under the laws of the State of New York and having a place of business in New York, New York.

14. Upon information and belief, Celltrion Healthcare Co., Ltd. and Celltrion, Inc. are companies organized and existing under the laws of the Republic of Korea. Celltrion, Inc. is a biopharmaceutical company that specializes in research and development of antibody biosimilars and biopharmaceuticals. Celltrion Healthcare Co., Ltd. markets and distributes such biopharmaceutical products in the United Sates. Celltrion Healthcare Co., Ltd. maintains an office for U.S. business operations in Cambridge, Massachusetts.

15. Upon information and belief, Hospira, Inc., is a Delaware corporation having corporate offices and a principal place of business in Lake Forest, Illinois.

JURISDICTION AND VENUE

16. This is an action for violations of 42 U.S.C. § 262(l), and patent infringement under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

17. On information and belief, Celltrion Healthcare Co., Ltd. intends to market and distribute its proposed biosimilar infliximab product in Massachusetts, through Hospira. On information and belief, Celltrion, Inc. will collaborate in the commercialization of the product in Massachusetts.

18. Celltrion Healthcare Co., Ltd. maintains an office for U.S. business operations in Cambridge, Massachusetts. On information and belief, among the purposes of this office is to market and distribute products manufactured by Celltrion, Inc. in collaboration with Celltrion, Inc.

19. Celltrion Healthcare Co., Ltd. is registered to do business in Massachusetts and has consented to be sued in Massachusetts. On information and belief, among the purposes of Celltrion Healthcare Co., Ltd.'s Massachusetts business is to market and distribute products manufactured by Celltrion, Inc. in collaboration with Celltrion, Inc.

20. Celltrion Healthcare Co., Ltd. and Celltrion, Inc. previously filed a Declaratory Judgment Complaint in this District against Janssen (*see Celltrion Healthcare Co., Ltd. and Celltrion, Inc. v. Janssen Biotech, Inc.*, No. 14-cv-11613 (D. Mass. filed Mar. 31, 2014)) involving the same proposed biosimilar product and two of the patents at issue in this Complaint. That declaratory judgment action was voluntarily dismissed by Celltrion on October 23, 2014 after Janssen's motion to dismiss was fully briefed.

21. This Court has personal jurisdiction over Celltrion Healthcare Co., Ltd. and Celltrion, Inc.

22. On information and belief, Hospira has been involved in an ongoing and continuing business relationship with Celltrion concerning their proposed biosimilar infliximab product since at least 2009. On information and belief, Hospira has been aware during that time that Celltrion maintains its office for U.S. business operations in Massachusetts.

23. On information and belief, Hospira entered into an exclusive license agreement and/or marketing agreement with Celltrion covering the proposed biosimilar infliximab.

24. On information and belief, Hospira is obligated, or entitled, to indemnify, defend, or participate in patent litigation brought against Celltrion related to the proposed biosimilar infliximab product. On information and belief, Hospira is actively collaborating with Celltrion in preparation for litigation concerning Defendants' proposed biosimilar infliximab product.

25. On information and belief, Hospira has collaborated with Celltrion in the submission of Defendants' aBLA and intends to market and distribute the proposed biosimilar infliximab product in Massachusetts.

26. On information and belief, Hospira is engaged in the distribution of generic pharmaceutical products throughout the world, including in Massachusetts.

27. On information and belief, Hospira has voluntarily and purposely directed its activities at residents of this forum, including by engaging in an ongoing and continuing business relationship with Celltrion, and by engaging in continuous and systematic activity in Massachusetts through its authorized distributors and a Customer Fulfillment Center in Massachusetts.

28. This Court has personal jurisdiction over Hospira.

29. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c) and/or 1400(b).

REMICADE® (INFLIXIMAB)

30. Janssen is a pioneer and leader in the development of biologic drugs. Janssen's biologic drug Remicade® was one of the first drugs of its kind sold in the United States for treatment of a chronic disease.

31. Remicade® is a monoclonal antibody that binds to and neutralizes a substance in our bodies called TNFα. TNFα is an important player in our immune systems but, if it is over-produced, it can lead to chronic disease.

32. Scientists at NYU worked with scientists at Janssen's predecessor Centocor to develop the infliximab monoclonal antibody, also known as the "cA2" antibody.

33. Although the cA2 antibody had promising in vitro properties, given its complex structure and mechanism of operation it required extensive pre-clinical and clinical development before it could become a useful medicine for human beings.

34. From the time the infliximab antibody was first discovered, it took nearly a decade for Remicade® to be approved for sale in the United States. During that time, Centocor conducted dozens of clinical trials and spent tens of millions of dollars, with no guarantee of success.

35. Remicade® was first approved for the U.S. market in 1998. The first indication, or use, for which Remicade® was approved was the treatment of Crohn's disease, an inflammatory bowel disease that causes inflammation of the lining of the digestive tract. Remicade® was the first biological therapy approved for Crohn's disease in the United States.

36. After Remicade® entered the market, Centocor continued to pursue extensive clinical development efforts for the drug. These efforts led to the discovery that Remicade® is safe and effective for a number of additional diseases and indications other than Crohn's disease.

37. Janssen's extensive development efforts have led to 16 FDA approvals for Remicade®, including indications for use in the treatment of Crohn's disease (1998), rheumatoid arthritis (1999), ankylosing spondylitis, a chronic inflammatory disease of the axial skeleton

(2004), psoriatic arthritis (2005), and ulcerative colitis, an inflammatory bowel disease (2006). Remicade® has changed the standard of care for the treatment of these diseases.

38. In total, Janssen has sponsored more than 170 clinical trials for Remicade®. Janssen has spent hundreds of millions of dollars in research and development of the drug.

39. Remicade® had been used to treat and improve the lives of more than 2.2 million patients suffering from chronic disease.

PLAINTIFFS' PATENTS ON INFLIXIMAB AND RELATED TECHNOLOGY

40. In the course of developing Remicade®, Janssen has obtained or exclusively licensed a number of patents related to infliximab, its uses in treating disease, and the processes for manufacturing infliximab. Plaintiffs assert six of these patents in this action.

The Antibody Patent (the 471 Patent)

41. Janssen and NYU jointly own United States Patent No. 6,284,471 ("the 471 patent"), which covers the infliximab cA2 monoclonal antibody itself. The cA2 antibody is a highly complex biological molecule that took years to develop and has highly potent healing properties.

42. On September 4, 2001, the United States Patent and Trademark Office ("PTO") issued the 471 patent, which is titled "Anti-TNFα Antibodies and Assays Employing Anti-TNFα Antibodies." A true and correct copy of the 471 patent is attached as Exhibit A.

43. The 471 patent is jointly assigned to Janssen (through its predecessors Centocor, Inc. and Centocor Ortho Biotech, Inc.) and NYU.

44. The 471 patent will expire on September 4, 2018.

45. In a prior proceeding, Defendants did not dispute that their proposed biosimilar infliximab product practices claims of the 471 patent.

46. The 471 patent is currently undergoing reexamination by the PTO.

47. On information and belief, one or more of the Defendants, or an agent or affiliate of one or more of the Defendants, initiated the PTO reexamination proceeding challenging the validity of the 471 patent.

48. In the reexamination, the specification of the 471 patent was amended at Janssen's request. A PTO examiner has rejected the claims of the 471 patent. Janssen is currently addressing the rejection.

The Fistulizing Crohn's Patent (the 396 Patent)

49. Janssen and NYU jointly own United States Patent No. 7,223,396 ("the 396 patent"). In contrast to the 471 patent, which covers the infliximab antibody itself, the claims of the 396 patent cover novel uses of infliximab to treat disease. In particular, the 396 patent covers specific methods of using infliximab to treat fistulas – abnormal connections or openings between two organs that are not normally connected – in patients with Crohn's disease.

50. On May 29, 2007, the PTO issued the 396 patent, which is titled "Methods of Treatment of Fistulas in Crohn's Disease with Anti-TNF Antibodies." A true and correct copy of the 396 patent is attached as Exhibit B.

51. The 396 patent is jointly assigned to Janssen (through its predecessors Centocor, Inc. and Centocor Ortho Biotech, Inc.) and NYU.

52. The 396 patent will expire on June 29, 2016.

53. In a prior proceeding, Defendants did not dispute that the proposed use of their product would practice the claims of the 396 patent.

54. It is unknown whether a U.S. approval of Defendants' proposed biosimilar product, if any, would include an indication for treating fistulas in Crohn's disease, as claimed by the 396 patent.

The Methods of Producing Antibodies Patent (the 715 Patent)

55. Janssen has exclusively licensed from Board of Trustees of the Leland Stanford Junior University ("Stanford") and the Trustees of Columbia University in the City of New York ("Columbia") U.S. Patent No. 5,807,715 ("the 715 patent"), which covers methods of producing functional antibodies that are capable of specifically binding antigens.

56. On September 15, 1998, the PTO issued the 715 patent, which is entitled "Methods And Transformed Mammalian Lymphocyte Cells For Producing Functional Antigen-Binding Protein Including Chimeric Immunoglobulin." A true and correct copy of the 715 patent is attached as Exhibit C.

57. Stanford and Columbia hold title to the 715 patent.

58. Janssen holds all substantial rights in the 715 patent, including the sole and exclusive right to initiate, control, and defend any patent infringement litigation under the BPCIA involving the 715 patent.

59. The 715 patent will expire on September 15, 2015.

The Chemical Cell Growth Media Patents (the 083 Patent and the 056 Patent)

60. Janssen owns U.S. Patent No. 7,598,083 ("the 083 patent") and U.S. Patent No. 6,900,056 ("the 056 patent"), which cover cell growth media for use in growing biological products, including infliximab.

61. On October 6, 2009, the PTO issued the 083 patent, entitled "Chemically Defined Media Compositions." A true and correct copy of the 083 patent is attached as Exhibit D.

62. On May 31, 2005, the PTO issued the 056 patent, entitled "Chemically Defined Medium for Cultured Mammalian Cells." A true and correct copy of the 056 patent is attached as Exhibit E.

63. The 083 patent will expire on February 7, 2027.

64. The 056 patent will expire on October 5, 2022.

The Purification Patent (the 600 Patent)

65. Janssen owns U.S. Patent No. 6,773,600 ("the 600 patent"), which covers novel methods of purifying biological products such as infliximab so that they are suitable for use in human medicines.

66. On August 10, 2004, the PTO issued the 600 patent, entitled "Use of Clathrate Modifier, To Promote Passage of Proteins During Nanofiltration." A true and correct copy of the 600 patent is attached as Exhibit F.

67. The 600 patent will expire on June 4, 2023.

BIOLOGICS, BIOSIMILARS, AND THE BPCIA

Biologics

68. Biological medicines, or biologics, are complex biological molecules that need to be grown in living cultures rather than chemically synthesized, as are the more familiar pharmaceutical products known as chemical or small-molecule drugs. Because the biologic manufacturing process is complex and uses living organisms, the structural features of a biologic drug can vary based on the precise manner in which the drug is made. Unlike small-molecule drugs, moreover, biological molecules generally cannot be completely characterized.

69. Because of the differences between biological and small-molecule drugs, biological and small-molecule pharmaceutical products are approved for sale in the United States

through different regulatory pathways. Whereas small-molecule drugs are approved based on the submission of a New Drug Application ("NDA") (*see* 21 U.S.C. § 355), biological products are assessed pursuant to a Biological License Application ("BLA") (*see* 42 U.S.C. § 262(a)).

The BPCIA Pathway for Biosimilar Approval

70. Although Congress created an abbreviated regulatory pathway for the approval of generic small-molecule drugs in the Hatch-Waxman Act of 1984, no abbreviated pathway for approval of follow-on biologics products existed until the enactment of the BPCIA, as part of the Patient Protection and Affordable Care Act, in 2010. Before the enactment of the BPCIA, the only way to obtain U.S. approval of a biological product was through an original BLA supported by a full complement of pre-clinical and clinical data.

71. The BPCIA creates an abbreviated approval pathway for FDA licensure of biological products upon a determination that the biological product is "biosimilar" to a previously licensed "reference product." 42 U.S.C. § 262(k). The BPCIA defines a "biosimilar" as a biological product that is (1) "highly similar to the reference product notwithstanding minor differences in clinically inactive components"; and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. §§ 262(i)(2)(A), (B). The BPCIA defines a "reference product" to be a "single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k)." 42 U.S.C. § 262(i)(4).

72. Under the BPCIA, biosimilar applicants are permitted to make use of FDA's prior determinations as to the safety, purity, and potency of the reference product that was already approved by FDA. In particular, a biosimilar applicant must identify a single reference product

that has already been approved by FDA and submit to FDA "publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent." 42 U.S.C. § 262(k)(2)(A)(iii)(I). Consequently, the § 262(k) pathway created by the BPCIA allows the biosimilar applicant to reduce the time, expense, and risks of research and development and the full complement of pre-clinical and clinical testing, and gain licensure to commercialize its biological product in the market as a biosimilar sooner and more cheaply than it could have done through the submission of an original BLA.

The BPCIA's Patent Dispute Resolution Procedures

73. As Congress expressly indicated, the purpose of the BPCIA is to establish "a biosimilars pathway balancing innovation and consumer interests." Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, § 7001(b), 124 Stat. 119, 804 (2010).

74. To further this goal, Congress created a set of mandatory procedures for addressing patent disputes relating to prospective biosimilar drugs. These procedures are set forth in 42 U.S.C. § 262(l) and in corresponding amendments to the patent infringement statute, 35 U.S.C. § 271. The procedures are intended to ensure that the maker of an innovative biological product that is the subject of a biosimilar application will have sufficient time and opportunity to enforce its patent rights before a biosimilar product enters the United States market. The BPCIA's patent dispute resolution procedures are also intended to ensure that disputes over patent rights will take place in an orderly fashion, with the least possible uncertainty, brinksmanship, and burden on the parties and the courts.

75. The BPCIA patent dispute resolution procedures require the biosimilar applicant and reference product sponsor to undertake a series of specific steps before any patent action is filed. Reflecting their importance to the BPCIA, most of these steps are mandatory and

unconditional: the statute states that the parties "shall" undertake them. *See* 42 U.S.C. §§ 262(l)(2)(A), (l)(3)(A), (l)(3)(B), (l)(3)(C), & (l)(4)(A). Where a specific action is optional or conditional, the statute makes this clear, stating that the parties "may" take such action, *see* 42 U.S.C. § 262(l)(2)(B), or that they shall do so only "[i]f" a specified condition precedent occurs, *see* 42 U.S.C. § 262(l)(4)(B).

76. The BPCIA dispute resolution process begins when a biosimilar application is accepted for review by FDA. Within twenty days thereafter, the biosimilar applicant "shall provide" the reference sponsor with confidential access to "a copy of the application submitted . . . under subsection (k), ***and*** such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(l)(2)(A) (emphasis added). This step initiates a series of pre-litigation exchanges of information and positions so that the parties may engage in mandatory good-faith negotiations regarding what patents should be litigated prior to the approval of the biosimilar product. *See* 42 U.S.C. § 262(l)(2)-(l)(6).

77. The requirement that biosimilars applicants provide pre-litigation manufacturing information to reference product sponsors, which does not exist for generic small-molecule drugs under the Hatch-Waxman Act, reflects the complexity of manufacturing processes for biologics and their importance to innovation in the field. To ensure that full application and manufacturing information be provided without prejudice or delay, the BPCIA sets forth a detailed set of confidential access provisions governing the reference product sponsor's use of the required information. 42 U.S.C. § 262(l)(1).

78. The next step in the statutory process, section 262(l)(3)(A), states that within 60 days the reference product sponsor "shall provide" the biosimilar applicant a list of patents that

the reference product sponsor "believes a claim of patent infringement could reasonably be asserted" against the proposed biosimilar product or the uses or manufacture of such product. 42 U.S.C. § 262(l)(3)(A)(i). The reference product sponsor is also required to indicate whether it is willing to license any of these patents. 42 U.S.C. § 262(l)(3)(A)(ii).

79. The next statutory step, section 262(l)(3)(B), states that within 60 days the biosimilar applicant "shall provide" a "detailed statement" of its non-infringement, invalidity, and unenforceability defenses with respect to the listed patents, or a statement that the subsection (k) applicant "does not intend to bring commercial marketing of the biological product before the date that such patent expires." 42 U.S.C. § 262(l)(3)(B)(ii).

80. The next step in the statutory process, section 262(l)(3)(C), states that within 60 days the reference product sponsor "shall provide" a "detailed statement" of its infringement positions and "a response to the statement concerning validity and enforceability provided" by the biosimilar applicant. 42 U.S.C. § 262(l)(3)(C).

81. The next step in the statutory process states that the parties "shall engage in good faith negotiations" to agree on patents that will be subject to an action for patent infringement prior to the approval of the biosimilar application. 42 U.S.C. § 262(l)(4)(A).

82. If the parties agree on the patents that will be subject to an immediate action for infringement, then the reference product sponsor "shall bring an action for patent infringement" within thirty days of the agreement. 42 U.S.C. § 262(l)(6)(A). If the parties fail to reach agreement, they proceed to a further exchange process that will identify one or more patents for immediate litigation. 42 U.S.C. § 262(l)(4)(B) & (l)(5). As in the case of agreement, the reference product sponsor "shall bring an action for patent infringement" within thirty days after patents are selected for litigation through this process. 42 U.S.C. § 262(l)(6)(B).

83. If the reference product sponsor fails to bring suit within thirty days of the selection of patents for immediate litigation, its "sole and exclusive remedy" will be "a reasonable royalty." 35 U.S.C. § 271(e)(6)(B).

Notice of Commercial Marketing

84. In addition to the pre-litigation procedures described above, the BPCIA addresses litigation regarding a "biological product licensed under subsection (k)" – i.e., a biosimilar product that has been approved for marketing. The BPCIA requires the biosimilar maker to provide "notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(1)(8)(A).

85. Upon receipt of a notice of commercial marketing, the reference product sponsor may move for a preliminary injunction on patents that the sponsor identified as potentially infringed under section 262(l)(3)(A) of the pre-litigation dispute resolution procedures, but which the parties have not selected for litigation pursuant to these procedures. 42 U.S.C. § 262(1)(8)(B).

86. In addition, the notice of commercial marketing permits the reference product sponsor to bring a declaratory judgment action with respect to such patents that have been identified but not selected for immediate litigation. 42 U.S.C. § 262(1)(9)(A). Before the notice of commercial marketing, such declaratory judgments are prohibited. *Id.*

CELLTRION'S PROPOSED BIOSIMILAR PRODUCT

87. On information and belief, Celltrion has undertaken the development of a proposed biosimilar to Janssen's Remicade® infliximab product. The trade name for the Celltrion proposed biosimilar product is Remsima®.

88. On information and belief, in 2009, Hospira entered into an agreement with Celltrion, pursuant to which Hospira obtained the rights to exclusively market biosimilar infliximab in the United States. The trade name for the proposed biosimilar infliximab product to be marketed by Hospira is Inflectra®.

89. On information and belief, Defendants submitted an Investigational New Drug ("IND") application for their proposed biosimilar to Janssen's infliximab product under section 505(i) of the Federal Food, Drug, and Cosmetic Act on October 2, 2013, and the FDA accepted the IND on November 18, 2013. Defendants submitted an aBLA for this proposed biosimilar product on or about August 8, 2014 and the FDA accepted that application for review on or about October 7, 2014.

90. On information and belief, the proposed indications (uses) for which Defendants seek approval of its biosimilar product are:

> (1) Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy; (2) reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease; (3) reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy; (4) reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy; (5) reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy; (6) in combination with methotrexate, reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis; (7) reducing signs and symptoms in patients with active ankylosing

> spondylitis; (8) reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis; and (9) treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

(U.S. Food and Drug Administration, POSTPONED: March 17, 2015: Arthritis Advisory Committee Meeting Announcement http://www.fda.gov/advisorycommittees/ucm433919.htm).

91. These proposed indications for Defendants' proposed biosimilar product are all indications for which Remicade® has been approved. Each of these nine indications results from extensive research and development by Plaintiffs, culminating in successful clinical trials demonstrating that Remicade® is safe and effective for these indications.

92. Based on publicly available information from Defendants' regulatory submissions in other countries, and from the clinicaltrials.gov database of clinical trials, Defendants have completed two Phase III clinical trials regarding the safety and efficacy of their proposed biosimilar product. One of these trials involved patients with rheumatoid arthritis and the other involved patients with ankylosing spondylitis. Neither of these two completed Phase III clinical trials for Defendants' proposed biosimilar product involved patients with Crohn's disease.

93. Defendants' proposed biosimilar infliximab product has been approved for sale in other jurisdictions, including Canada. In approving Defendants' product, the Canadian health authorities elected not to approve an indication for the treatment of Crohn's disease. The Canadian health authorities stated that "extrapolation of data from the settings of rheumatoid arthritis and [ankylosing spondylitis] to adult and pediatric inflammatory bowel diseases (Crohn's disease, ulcerative colitis) was not recommended." (Summary Basis for Decision, Remsima, http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd_smd_2014_remsima_160195-eng.php).

94. On information and belief, FDA has not yet decided whether to approve Defendants' proposed biosimilar product or what indications to approve it for. Nor has FDA identified any timetable for a decision on Defendants' aBLA.

95. FDA had planned to consider Defendants' proposed product in a public, full-day meeting of its Arthritis Advisory Committee that was originally scheduled for March 17, 2015. *See* http://www.fda.gov/advisorycommittees/ucm433919.htm. Typically, FDA advisory committees vote whether to recommend approval, and what indications to recommend approval for, on the day of their meeting. Although these recommendations are not binding on FDA, they are usually followed.

96. On February 25, 2015, however, FDA postponed the scheduled advisory committee meeting on Defendants' proposed biosimilar product indefinitely. FDA's postponement announcement reads in its entirety: "The Food and Drug Administration (FDA) is postponing the meeting of the Arthritis Advisory Committee scheduled for March 17, 2015. The postponement is due to information requests pending with the sponsor of the application. A future meeting date will be announced in the Federal Register." *See* http://www.fda.gov/advisorycommittees/ucm433919.htm.

DEFENDANTS' EFFORTS TO AVOID THE BPCIA'S PATENT DISPUTE RESOLUTION PROCEDURES

97. From the time they began the process of seeking approval for their proposed biosimilar product, Defendants have sought to avoid the mandatory patent dispute resolution procedures of the BPCIA. Having failed in their initial efforts to bypass the BPCIA procedures altogether by filing premature declaratory judgment actions, Defendants have now proceeded to short-circuit the statutory process by withholding required information, by refusing to participate to date in required statutory procedures, and by serving a premature notice of commercial

marketing that, unless declared ineffective, would thwart the statutory purpose of litigating actual disputes and burden the parties and the Court with unnecessary litigation.

98. On information and belief, Defendants have participated jointly in formulating Defendants' pre-litigation and litigation strategy under the BPCIA.

Defendants Try Unsuccessfully to Bypass the BPCIA's Procedures

99. As alleged above, the BPCIA's dispute resolution procedures are triggered by FDA's acceptance of a biosimilar application for review. 42 U.S.C. § 262(1)(2)(A). Before Celltrion's application was accepted for review by FDA, Celltrion and Hospira each tried to circumvent the BPCIA by filing separate declaratory judgment actions seeking declarations of noninfringement or invalidity of patents that Celltrion and Hospira unilaterally identified as potentially relevant to their proposed biosimilar product. *See Celltrion Healthcare Co., Ltd., and Celltrion, Inc., v. Janssen Biotech, Inc.*, No. 14-cv-11613 (D. Mass.); *Hospira, Inc. v. Janssen Biotech, Inc. et al.*, No. 14-cv-07049 (S.D.N.Y.).

100. In both actions, Janssen moved to dismiss on the grounds that a declaratory judgment action was prohibited since Defendants could not seek a declaratory judgment before producing their aBLA and without following the requirements of the BPCIA. In response, Defendants contended that the BPCIA procedures have no effect prior to FDA's acceptance for review of the aBLA. According to Defendants, a prospective biosimilar applicant is entitled to bypass the BPCIA procedures by filing a declaratory judgment action concerning the patents it believes the patent holder will assert against the proposed biosimilar product, so long as the action is filed before the aBLA is accepted for review. Hospira also argued that the BPCIA litigation procedures were not applicable to it at any point.

101. Judge Crotty of the U.S. District Court for the Southern District of New York granted Janssen's motion to dismiss Hospira's declaratory judgment action. Judge Crotty rejected Hospira's argument that it was entitled to bring a declaratory judgment action without following the BPCIA patent dispute resolution procedures.

102. Judge Crotty reasoned that Hospira "seeks to utilize the BPCIA pathway for approval of its biosimilar drug, yet disavows the BPCIA's authority over patent disputes. Despite Hospira's best attempts to twist the BPCIA to serve its interests without hindering its pursuit of litigation, this effort fails." *Hospira, Inc. v. Janssen Biotech, Inc*., 113 U.S.P.Q.2d 1260, 1262 (S.D.N.Y. 2014). Judge Crotty stated that the "BPCIA purposefully ties the dispute resolution process to events throughout the biosimilar approval process, ensuring that full information exchange occurs at relevant and crucial periods during the approval process." *Id.* Judge Crotty concluded that permitting Hospira's declaratory judgment action to proceed would allow biosimilar applicants to "skirt the dispute resolution procedures Congress purposefully enacted" for patent disputes arising from the filing of a biosimilar application under the BPCIA. *Id.*

103. Celltrion voluntarily withdrew its declaratory judgment action after Janssen's motion to dismiss was fully briefed. *See Celltrion Healthcare Co., Ltd., and Celltrion, Inc., v. Janssen Biotech, Inc.*, No. 14-cv-11613 (D. Mass.) (Dkt. No. 33) (Oct. 23, 2014).

Defendants Refuse to Provide Required Manufacturing Information

104. Pursuant to section 262(l)(2)(A) of the BPCIA, Defendants began to provide Janssen with a copy of their aBLA (No. 125544) twenty days after the application was accepted for review by FDA. However, Defendants have refused to prove "such other information that describes the process or processes used to manufacture the biological product that is the subject

of such application" as required by the statute. Defendants provided Janssen only with their aBLA and nothing else.

105. On December 16, 2014, before its time for providing its section 262(l)(3)(A) listing of potentially infringed patents, Janssen asked Defendants to provide the manufacturing information required by the statute. Janssen also asked specific, detailed questions about Celltrion's manufacturing processes.

106. On December 23, 2014, Defendants responded by refusing to provide the requested information. Despite the statutory requirement that biosimilar applicants provide their aBLA ***and*** additional manufacturing information, Defendants asserted that "[a]ll relevant information needed to generate a list of patents for which a claim of patent infringement can reasonably be asserted by Janssen is included in Celltrion's [a]BLA." Defendants did not provide any additional manufacturing information.

107. On December 26, 2014, Janssen provided Defendants a list of patents for which a claim of infringement could reasonably be asserted pursuant to section 262(l)(3)(A) of the BPCIA patent dispute resolution process. 42 U.S.C. § 262(l)(3)(A). This list included the cell growth media patents (the 083 patent and the 056 patent) and the purification patent (the 600 patent).

108. On February 5, 2015, Defendants provided a statement of defenses pursuant to 42 U.S.C. § 262(l)(3)(B). Defendants did not produce any documentation of their manufacturing processes as required by 42 U.S.C. § 262(l)(2)(A).

109. On February 25, 2015, Janssen asked Defendants again for the manufacturing information that is required by the statute, and which Janssen had previously requested on December 16, 2014.

110. On March 4, 2015, Defendants responded by asserting once again that the aBLA contained all the information to which Plaintiffs were entitled, notwithstanding the BPCIA's unambiguous requirement that manufacturing information in addition to the aBLA be provided. Defendants refused to provide documentation of their manufacturing processes prior to any lawsuit as required under the BPCIA, contending that "Celltrion does not have the authority" to disclose certain information about the ingredients, such as the cell media, used in its product manufacture, and instead insisting that Janssen's request for such information "be addressed after suit is filed."

Defendants Attempt to Circumvent Mandatory BPCIA Procedures

111. As of their statement of defenses pursuant to 42 U.S.C. § 262(l)(3)(B), Defendants have refused to participate in further BPCIA patent dispute resolution procedures including the good-faith negotiations regarding patents to be included in immediate litigation pursuant to 42 U.S.C. § 262(l)(4).

112. Defendants assert that they have "consented to Janssen's patent list" and that as a result the remainder of the statutorily required patent-exchange procedures – namely Janssen's mandatory responses to Defendants' defenses pursuant to section 262(1)(3)(C) , the parties' mandatory good-faith negotiations under section 262(1)(4), and the procedures for identifying the patents to be immediately litigated in the absence of an agreement – are moot. *See* 42 U.S.C. § 262(1)(3)-(l)(5). Defendants have stated that they will not engage in good-faith negotiations with Janssen as required by 42 U.S.C. § 262(1)(4).

113. Defendants further assert that Janssen is required to file a lawsuit on all six listed patents within thirty days of Defendants' "detailed statement," i.e., by March 7, 2015, rather than within thirty days after the completion of the statutory pre-litigation procedures, as the BPCIA

requires. Defendants have asserted that if Janssen did not file suit within this time, its remedy in any later suit would be limited to reasonable royalty damages pursuant to 35 U.S.C. § 271(e)(6)(B).

114. Defendants' assertion that Janssen needed to file suit immediately or be limited to reasonable royalties was a clear threat to take this position in future litigation, and to require Janssen, if it did not meet Defendants' demands, to litigate the issue at the risk of losing its right to injunctive relief or lost profits. On information and belief, Defendants have repudiated their obligations under the BPCIA and made this legally baseless threat in the hope of compelling Janssen to file this action within the time period Defendants demanded, rather than at the time required by the BPCIA.

115. On February 25, 2015, Janssen asked Defendants to withdraw their threat and comply with the BPCIA's mandatory procedures.

116. On March 4, 2015, Defendants responded by reaffirming their position that Janssen is required to file suit by March 7, 2015 and reserving the "the right to limit Janssen's remedy for any judgment of infringement to a reasonable royalty" if "Janssen elects not to bring suit by March 7, 2015." Defendants offered to refrain from doing so as a "compromise" if "and only if" Janssen agreed to bring suit by April 6, 2015, prior to the mandatory good-faith negotiations that are a prerequisite to filing suit under the BPCIA. This proposed "compromise" was just another refusal to comply with mandatory BPCIA procedures. Defendants coupled that proposal with a variety of other unacceptable demands that violate the BPCIA. These included the insistence that Plaintiffs seek preliminary injunctions on patents that are premature to litigate.

117. Given Defendants' threat to Plaintiffs' intellectual property rights and refusal to comply with the provisions of the BPCIA, Plaintiffs have filed this Complaint to protect their

interests and enforce the mandatory statutory provisions which Defendants seek to bypass. As a direct result of Defendants' wrongful conduct, Plaintiffs are being compelled to assert patent infringement claims that might never have needed to be litigated or, with respect to the 471 patent, would have been litigated in a different form had Defendants complied with the BPCIA.

118. Had Defendants complied with the BPCIA, the parties' mandatory good-faith negotiations (42 U.S.C. § 262(l)(4)) might have led to an agreement to postpone litigation of the 471 patent, covering the cA2 antibody, until the conclusion of the PTO reexamination proceeding that, on information and belief, was brought by one or more of Defendants or their agents or affiliates. If the 471 patent is upheld in reexamination (as Janssen and NYU believe it will be), it would be litigated in a form that is different from the patent today since the 471 patent specification has been amended in the reexamination proceeding.

119. Had Defendants complied with the BPCIA, the parties' mandatory good-faith negotiations might have led to an agreement to postpone litigation of the 396 patent, covering methods for treating fistulas in Crohn's disease, until FDA determined whether Defendants' proposed biosimilar product would receive an indication for treating fistulas in Crohn's disease. If FDA determines that Defendants' product should not receive such an indication – a significant possibility since the Canadian health authorities recently arrived at that very conclusion – the 396 patent would never need to be litigated.

120. Had Defendants complied with the BPCIA, the parties' mandatory good-faith negotiations might have led to an agreement to avoid litigating the 715 patent, which expires on September 15, 2015. In light of FDA's recent decision to indefinitely postpone the advisory committee meeting on Defendants' proposed biosimilar product, it is unlikely that Defendants' proposed product will even be approved, much less ready to be marketed, by September 15,

2015. Defendants have all but acknowledged this, asserting on March 4, 2015 that they would agree to "delay commercial marketing of the infliximab biosimilar product pursuant to aBLA 125544 until after September 15, 2015" – but only as part of a "compromise" in which Janssen would agree to disregard mandatory requirements of the BPCIA and burden the Court with premature and wasteful preliminary injunction motions on patents that might never need to be litigated, or might never need to be litigated in their current form.

121. Had Defendants complied with the BPCIA, the parties' mandatory good-faith negotiations might have led to the production of information that would have avoided the need to litigate Janssen's manufacturing patents – the cell growth media patents (the 083 patent and the 056 patent) and the purification patent (the 600 patent). Instead, in violation of the BPCIA, Defendants have proposed providing further information only after Janssen files suit.

122. Defendants' violations of the BPCIA have caused and will cause unnecessary burdens to Plaintiffs and the Court. Defendants' violations of the BPCIA have caused Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless these statutory requirements are enforced by this Court. Plaintiffs have been and will continue to be injured by Defendants' actions.

Defendants Serve a Premature Notice of Commercial Marketing

123. On February 5, 2015, the same day they provided their "detailed statement" to Janssen, Defendants compounded their violations of the BPCIA by serving a premature notice of commercial marketing, purportedly pursuant to 42 U.S.C. § 262(l)(8)(A). Defendants asserted that they would begin commercial marketing of their proposed biosimilar product "as early as 180 days from the date of this notice," i.e., August 4, 2015.

124. Prior to their purported "notice of commercial marketing" of February 5, 2015, Defendants had previously asserted that a different document constituted a notice of commercial marketing under the BPCIA. In briefing in its unsuccessful declaratory judgment action, Hospira asserted that Celltrion's declaratory judgment complaint alleging that it intended to sell its proposed biosimilar infliximab product in the United States "should satisfy the Act's notice provision, which does not prescribe any particular form." *See Hospira, Inc. v. Janssen Biotech, Inc.*, No. 14-cv-7059 (S.D.N.Y. Oct. 16, 2014) (Dkt. No. 42 at 22).

125. In their latest purported notice of commercial marketing of February 5, 2015, Defendants asserted that the BPCIA does not "include a condition precedent to providing notice." But, to the contrary, the BPCIA includes a clear condition precedent to providing a notice of commercial marketing. The statutorily required notice is "of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(l)(8)(A). The grant of a license under subsection (k) is a statutory prerequisite to providing a notice of commercial marketing.

126. As Defendants are aware, this was precisely the holding of the sole reported case to address this issue to date. *See Sandoz Inc. v. Amgen Inc.*, No. C-13-2904 MMC, 2013 U.S. Dist. LEXIS 161233 (N.D. Cal. Nov. 12, 2013). As Judge Chesney of the United States District Court for the Northern District of California concluded, a biosimilar applicant "cannot, as a matter of law, have provided a 'notice of commercial marketing'" prior to obtaining a biological license because until that time the biosimilar product "is not 'licensed under subsection (k).'" *Id.* at *6.

127. Defendants have not yet received a license to market their proposed biosimilar product under subsection (k). As a result, Defendants' proposed product is not a "biological

product licensed under subsection (k)" and cannot be the subject of a valid notice of commercial marketing pursuant to the BPCIA.

128. The purpose of the notice of commercial marketing provision is to provide the parties and the Court with sufficient time – 180 days – to resolve any disputes that need to be resolved before commercial launch of a biosimilar product. If Defendants are allowed to proceed based on their invalid notice of commercial marketing, the 180 day period would run during a time when the precise nature of the dispute between the parties, and even the need for litigation on certain patents, has not yet crystallized.

129. With respect to the 471 patent, there is a pending reexamination proceeding in which the specification of the patent has been amended. By the time Defendants' product is licensed and a notice of commercial launch is permitted under the BPCIA, the 471 patent may have emerged from the reexamination proceeding and would be litigated in its amended form.

130. With respect to the 396 patent, there is significant uncertainty whether Defendants' product, even if approved, will be approved for the method of treating fistulizing Crohn's disease claimed in the patent. If Defendants do not obtain an indication for fistulizing Crohn's disease, as they failed to do in Canada, by the time that Defendants' proposed biosimilar is licensed and a notice of commercial launch is permitted under the BPCIA, the 396 patent may never need to be litigated.

131. With respect to the 715 patent, the patent's September 15, 2015 expiration date makes any litigation almost certainly unnecessary since it is highly unlikely that Defendants' product will be approved 180 days prior to the expiration of the 715 patent.

132. With respect to the manufacturing patents, litigation may never need to have been brought because the production of manufacturing information as required under the BPCIA may reveal that the patents are not infringed.

133. By filing a premature notice of commercial marketing, Defendants have burdened the parties and the Court with premature litigation. They also deprived Plaintiffs of the orderly and certain process for protecting their patent rights under the BPCIA procedures.

134. On February 25, 2015, Janssen asked Defendants to withdraw their premature notice of commercial marketing.

135. On March 4, 2015, Defendants refused to withdraw the notice of commercial marketing. Defendants offered, as part of a "compromise," to agree to an accelerated schedule for litigating the parties' dispute over the effectiveness of Defendants' purported notice of commercial marketing.

136. Defendants' premature notice of commercial marketing has caused Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless the notice of commercial marketing is declared invalid by this Court. Plaintiffs have been and will continue to be injured by Defendants' actions.

COUNT 1: VIOLATION OF MANDATORY PROCEDURES UNDER 42 U.S.C. § 262(l)

137. Plaintiffs incorporate by reference paragraphs 1-136 as if fully set forth herein.

138. This claim arises under the BPCIA, 42 U.S.C. § 262(l), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) & 2202.

139. The BPCIA, 42 U.S.C. § 262(l), requires Plaintiffs and Defendants to follow mandatory procedures to resolve patent disputes related to the filing of an aBLA under 42 U.S.C. § 262(k).

140. Defendants have failed to comply with the mandatory requirements of the BPCIA. Defendants' violations of the BPCIA have injured Plaintiffs by depriving them of the procedural protections of the statute and by subjecting them to the burden of unnecessary litigation.

141. Under 42 U.S.C. § 262(l)(2)(A), Defendants were required to provide Janssen, within twenty days of when Defendants' aBLA was accepted for review, with a copy of the aBLA "and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." Defendants failed to provide such information in violation of the BPCIA.

142. Under 42 U.S.C. § 262(l)(4), Defendants were required to engage in good-faith negotiations with Janssen concerning which patents should be subject to immediate litigation. Defendants were required to engage in these good-faith negotiations after Janssen provided the information required by 42 U.S.C. § 262(l)(3)(C). Defendants are trying to circumvent the requirement for good-faith negotiations in violation of the BPCIA.

143. Under 42 U.S.C. § 262(l)(6), any patent litigation must be brought within 30 days of the completion of the good-faith negotiations, at a time when both parties have a better understanding of their respective positions and so do not burden the courts with unnecessary litigation. Defendants have forced Plaintiffs into filing premature patent claims by making baseless arguments that the failure to do so will cause Plaintiffs to lose valuable statutory rights.

144. Defendants' violations of the BPCIA's mandatory procedures, individually and collectively, have caused and will cause Plaintiffs injury, including irreparable harm for which Plaintiffs have no adequate remedy at law, and will continue unless the statutory requirements are declared and enforced by this Court.

COUNT 2: VIOLATION OF 42 U.S.C. § 262(l)(8)(A)

145. Plaintiffs incorporate by reference paragraphs 1-144 as if fully set forth herein.

146. This claim arises under the BPCIA, 42 U.S.C. § 262(l), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) & 2202.

147. Under 42 U.S.C. § 262(l)(8)(A), Defendants are required to provide notice to Janssen "not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." Defendants have violated this provision by purporting to serve a notice of commercial marketing even though their proposed biological product is not "licensed under subsection (k)."

148. Defendants' violation of 42 U.S.C. § 262(l)(8)(A) has caused and will cause Plaintiffs injury, including irreparable harm for which Plaintiffs have no adequate remedy at law, and will continue unless the statutory requirements are declared and enforced by this Court.

* * *

As a result of Defendants' violations of the BPCIA alleged above, Plaintiffs assert the following claims of patent infringement, which Plaintiffs believe are premature under the BPCIA, in order to preserve their rights to seek lost profits and injunctive relief.

COUNT 3: INFRINGEMENT OF THE 471 PATENT

149. Plaintiffs incorporate by reference paragraphs 1-148 as if fully set forth herein.

150. Upon information and belief, Defendants have been aware of the 471 patent since a time before Defendants filed their aBLA.

151. Defendants' submission of their aBLA was an act of infringement of the 471 patent under 35 U.S.C. § 271(e)(2)(C)(i), literally or under the doctrine of equivalents.

152. Defendants do not dispute that they infringe claims of the 471 patent.

153. Upon information and belief, Celltrion's and/or Hospira's commercial manufacture, use, sale, offer for sale and/or importation of their proposed biosimilar infliximab would infringe, contribute to the infringement of, and/or induce the infringement of claims 1, 3, and 5-7 of the 471 patent, literally or under the doctrine of equivalents.

154. Upon information and belief, Defendants' infringement of claims 1, 3, and 5-7 of the 471 patent would be objectively reckless and would make this case exceptional entitling Plaintiffs to attorneys' fees.

155. Unless Defendants are enjoined from infringing claims 1, 3, and 5-7 of the 471 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT 4: INFRINGEMENT OF THE 396 PATENT

156. Plaintiffs incorporate by reference paragraphs 1-155 as if fully set forth herein.

157. Upon information and belief, Defendants have been aware of the 396 patent since a time before Defendants filed their aBLA.

158. Defendants' submission of their aBLA was an act of infringement of the 396 patent under 35 U.S.C. § 271(e)(2)(C)(i), literally or under the doctrine of equivalents.

159. Defendants do not dispute that they infringe claims of the 396 patent.

160. Upon information and belief, Celltrion's and/or Hospira's commercial manufacture, use, sale, offer for sale and/or importation of their proposed biosimilar infliximab would infringe, contribute to the infringement of, and/or induce the infringement of claims 5, 7-9 and/or 29 of the 396 patent, literally or under the doctrine of equivalents.

161. Through their intended labelling, product inserts, publications, websites and/or promotional materials, Defendants will instruct customers to use their proposed biosimilar infliximab in an infringing manner. Specifically, Defendants will encourage infringement of

claims 5, 7-9 and/or 29 of the 396 patent. Defendants have knowledge of the 396 patent and know or are willfully blind to the possibility that the uses indicated and promoted on their intended labeling, product inserts, publications, websites and/or promotional materials encourage infringement of the aforementioned claims of the 396 patent.

162. Upon information and belief, Defendants' infringement of claims 5, 7-9 and/or 29 of the 396 patent would be objectively reckless and would make this case exceptional entitling Plaintiffs to attorneys' fees.

163. Unless Defendants are enjoined from infringing claims 5, 7-9 and/or 29 of the 396 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT 5: INFRINGEMENT OF THE 715 PATENT

164. Janssen incorporates by reference paragraphs 1-163 as if fully set forth herein.

165. On information and belief, Defendants have been aware of the 715 patent since a time before Defendants filed their aBLA.

166. Defendants' submission of their aBLA was an act of infringement of the 715 patent under 35 U.S.C. § 271(e)(2)(C)(i), literally or under the doctrine of equivalents.

167. Upon information and belief, Celltrion's and/or Hospira's commercial manufacture, use, sale, offer for sale and/or importation of their proposed biosimilar infliximab would infringe, contribute to the infringement of, and/or induce the infringement of claims of the 715 patent, literally or under the doctrine of equivalents.

168. Upon information and belief, Defendants' infringement of claims of the 715 patent would be objectively reckless and would make this case exceptional entitling Janssen to attorneys' fees.

169. Unless Defendants are enjoined from infringing claims of the 715 patent, Janssen will suffer irreparable injury for which damages are an inadequate remedy.

COUNT 6: INFRINGEMENT OF THE 083 PATENT

170. Janssen incorporates by reference paragraphs 1-169 as if fully set forth herein.

171. On information and belief, Defendants have been aware of the 083 patent since a time before Defendants filed their aBLA.

172. Defendants' submission of their aBLA was an act of infringement of the 083 patent under 35 U.S.C. § 271(e)(2)(C)(ii), literally or under the doctrine of equivalents.

173. Upon information and belief, Defendants' infringement of the 083 patent would be objectively reckless and would make this case exceptional entitling Janssen to attorneys' fees.

174. Unless Defendants are enjoined from infringing the 083 patent, Janssen will suffer irreparable injury for which damages are an inadequate remedy.

COUNT 7: INFRINGEMENT OF THE 056 PATENT

175. Janssen incorporates by reference paragraphs 1-174 as if fully set forth herein.

176. On information and belief, Defendants have been aware of the 056 patent since a time before Defendants filed their aBLA.

177. Defendants' submission of their aBLA was an act of infringement of the 056 patent under 35 U.S.C. § 271(e)(2)(C)(ii), literally or under the doctrine of equivalents.

178. Upon information and belief, Defendants' infringement of the 056 patent would be objectively reckless and would make this case exceptional entitling Janssen to attorneys' fees.

179. Unless Defendants are enjoined from infringing the 056 patent, Janssen will suffer irreparable injury for which damages are an inadequate remedy.

COUNT 8: INFRINGEMENT OF THE 600 PATENT

180. Janssen incorporates by reference paragraphs 1-179 as if fully set forth herein.

181. On information and belief, Defendants have been aware of the 600 patent since a time before Defendants filed their aBLA.

182. Defendants' submission of their aBLA was an act of infringement of the 600 patent under 35 U.S.C. § 271(e)(2)(C)(ii), literally or under the doctrine of equivalents.

183. Upon information and belief, Defendants' infringement of the 600 patent would be objectively reckless and would make this case exceptional entitling Janssen to attorneys' fees.

184. Unless Defendants are enjoined from infringing the 600 patent, Janssen will suffer irreparable injury for which damages are an inadequate remedy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor against Defendants and grant the following relief:

(a) a declaration that Defendants have failed to comply with the requirements of the BPCIA patent dispute resolution process, including 42 U.S.C. § 262(l)(2)(A) and 42 U.S.C. § 262(l)(4);

(b) an order compelling Defendants to comply with the BPCIA patent dispute resolution process set forth in 42 U.S.C. § 262(l);

(c) a declaration that the "notice of commercial marketing" provided by Defendants on February 5, 2015 is not an effective "notice of commercial marketing" within the meaning of 42 U.S.C. § 262(l)(8)(A) and that Defendants may not begin the commercial marketing of their proposed biosimilar to Janssen's Remicade® infliximab product until at least 180 days after Defendants provide Janssen with proper notice pursuant to 42 U.S.C. § 262(l)(8)(A) that Defendants have received a license for and intend to begin commercial marketing of the product;

(d) preliminary and/or permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins Defendants, their officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns, from any commercial manufacture, use, offer to sell or sale within the United States, of Defendants' proposed biosimilar to Janssen's Remicade® infliximab product, until 180 days after Defendants provide Janssen with proper notice pursuant to 42 U.S.C. § 262(l)(8)(A) that Defendants have received a license for and intend to begin commercial marketing of the product;

(e) a judgment that Defendants have infringed under 35 U.S.C. § 271(e)(2)(C)(i):

(1) the 471 patent;
(2) the 396 patent; and
(3) the 715 patent;

(f) a judgment that Defendants have infringed under 35 U.S.C. § 271(e)(2)(C)(ii):

(1) the 083 patent;
(2) the 056 patent; and
(3) the 600 patent;

(g) a judgment declaring that the making, using, selling, offering to sell, or importing of the proposed biosimilar to Janssen's Remicade® infliximab product described in aBLA No. 125544 would constitute infringement of:

(1) the 471 patent;
(2) the 396 patent;
(3) the 715 patent;
(4) the 083 patent;
(5) the 056 patent; and
(6) the 600 patent;

(h) preliminary and/or permanent equitable relief, including but not limited to a preliminary and/or permanent injunction that enjoins Defendants, their officers, partners, agents,

servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United Sates, of any product that infringes, or the use or manufacture of which infringes:

(1) the 471 patent;
(2) the 396 patent;
(3) the 715 patent;
(4) the 083 patent;
(5) the 056 patent; or
(6) the 600 patent;

(i) an order compelling Defendants to compensate Plaintiffs for and awarding damages incurred as a result of Defendants' actions or inactions;

(j) a declaration that this is an exceptional case and an award to Plaintiffs of their attorneys' fees, costs and expenses pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(k) such other relief as this Court may deem just and proper.

Dated: March 6, 2015

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